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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,606	09/07/1999	ANDREW D. MURDIN	1038-971-MIS	8817
7590 12/10/2003 SIM & MCBURNEY 330 UNIVERSITY AVENUE 6TH FLOOR TORONTO, M5G1R7 CANADA			EXAMINER CHEN, SHIN LIN	
			ART UNIT 1632	PAPER NUMBER
DATE MAILED: 12/10/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/391,606

Applicant(s)

MURDIN ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003 and 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6, 8, 10-12 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 10-12 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-28-03 has been entered.

Applicants' amendment filed 11-19-03 has been entered. Claims 2, 4, 5, 7, 9, 13-17 and 21-23 have been canceled. Claims 1, 6, 10-12 and 18 have been amended. Claims 1, 3, 6, 8, 10-12 and 18-20 are pending and claims 1, 6, 10-12 and 18-20 are under consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 6, 10-12 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "said second nucleotide sequence encodes the 76 kDa protein having a molecular size of about 35 kDa and having SEQ ID No. 7" in claim 10 is vague and renders the claim indefinite. It is unclear how a nucleotide sequence encodes a 76 kDa protein also encodes a 35 kDa protein. Changing the phrase to "said second nucleotide sequence is 76 kDa protein gene sequence encoding a protein having molecular size of about 35 kDa and having SEQ ID No. 7" would be remedial.

Art Unit: 1632

The phrase “said second nucleotide sequence encodes the 76 kDa protein having a molecular size of about 60 kDa and having SEQ ID No. 8 or 9” in claim 11 is vague and renders the claim indefinite. It is unclear how a nucleotide sequence encodes a 76 kDa protein also encodes a 60 kDa protein. Changing the phrase to “said second nucleotide sequence is 76 kDa protein gene sequence encoding a protein having molecular size of about 60 kDa and having SEQ ID No. 8 or 9” would be remedial.

The phrase “said first nucleotide sequence being selected from those having SEQ ID Nos. 12, 13, or 14, 15 and 16” in claim 1 lines 5-7 is vague and renders the claim indefinite. It is unclear what sequence is intended to be selected from, SEQ ID No. 12 or 13, or SEQ ID No. 14 or 15, or SEQ ID No. 16, or a combination of sequences is intended, for example, combination of SEQ ID No. 12 or 13 and SEQ ID NO. 16, or combination of SEQ ID No. 14 or 15 and SEQ ID No. 16. Changing the phrase to “said first nucleotide sequence being selected from the group consisting of SEQ ID Nos. 12, 13 and 14” would be remedial. SEQ ID Nos. **15 and 16** are protein sequences **not nucleotide sequences**, it is unclear how to select a nucleotide sequence from protein sequences.

Similarly, the phrase “said second nucleotide sequence being selected from those having SEQ ID Nos. 1, 2, 3, or 4” in claim 1 lines 12-13 is vague and renders the claim indefinite. Changing the phrase to “said second nucleotide sequence being selected from the group consisting of SEQ ID Nos. 1, 2, 3 and 4” would be remedial. Claims 6, 10-12 and 18-20 depend on claim 1 but fail to clarify the indefiniteness.

The phrase “upon administration of the composition to the host is not adversely affected by the other” in claim 19 is vague and renders the claim indefinite. It is unclear whether the

Art Unit: 1632

phrase “the other” refers to vectors in claim 1 or any other vector or other compositions. If the phrase “the other” refers to any other vector or other compositions, then there is no antecedent basis for the phrase “the other”.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of a plasmid encoding the disclosed MOMP and a plasmid encoding the disclosed 76 kDa of *C. Pneumoniae* before challenge of *C. Pneumoniae*, and induction of a protective immune response against sublethal *C. Pneumoniae* lung infection in mice, does not reasonably provide enablement for an immunogenic composition comprising first and second vectors in amounts that individual protective effect of each vector upon administration to a host is not adversely affected by any other vector or any other composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 19 is directed to an immunogenic composition comprising first and second vectors of claim 1 in amounts that individual protective effect of each vector upon administration to a host is not adversely affected by the other.

Here, the phrase “the other” is interpreted as any other vector or any other composition. The claims encompass using any vector encoding any protein or a composition comprising said

Art Unit: 1632

vector. The specification only disclose amounts of a vector encoding a MOMP and a vector encoding a 76 kDa protein and the individual effect of each vector upon administration of said vectors to a host is not affected by the other vector of said two vectors set forth above. The specification fails to provide adequate guidance and evidence for the amounts of the vector encoding a MOMP or the vector encoding a 76 kDa protein such that the individual protective effect of the vector upon administration to a host would not be adversely affected by any other vector encoding any protein or any other composition comprising any vector. It was known in the art at the time of the invention whether a vector encoding any protein or a composition comprising any vector would adversely interfere the effect of the vector encoding a MOMP or the vector encoding a 76 kDa protein was unpredictable. Different proteins have different chemical structures and biological functions and can stimulate different immune responses in a host or interact with other proteins differently. How vectors encoding these different proteins interact or interfere with the vector encoding a MOMP or the vector encoding a 76 kDa protein depend on the chemical structures and biological functions of these proteins. It was unpredictable whether any vector encoding any protein or any composition comprising said vector would not adversely affect the effect of the vector encoding a MOMP or the vector encoding a 76 kDa protein. It was also unpredictable at what amount of any vector encoding any protein or any composition comprising said vector would not adversely affect the effect of the vector encoding a MOMP or the vector encoding a 76 kDa protein in a host. In view of the reasons set forth above, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that it would require one skilled in the art at the time of

Art Unit: 1632

the invention to engage in undue experimentation to practice over the full scope of the invention claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. Due to the move of USPTO to new site in Alexandria, Virginia, examiner's telephone number will be changed to (571) 272-0726 **after January 12, 2004**. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

